REMARKS

This Response is submitted in reply to the final Office Action mailed on January 11, 2005. Claims 1-12, 19-22 and 26-29 are pending in this application. In the Office Action, Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §112, second paragraph. For the reasons set forth below, Applicants respectfully submit that the rejection should be withdrawn.

In the Office Action, Claim 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The standard for determining whether the definitiveness requirement is met under 35 U.S.C. § 112, second paragraph, is "whether those skilled in the art would understand what is claimed when the claim is read in light of the Specification." *Orthokinetics Inc. v. Safety Travel Chairs Inc,* 1 U.S.P.Q. 2d 1081-1088 (Fed. Cir. 1986). Applicants respectfully disagree with the Patent Office's rejection under 35 U.S.C. § 112, second paragraph, and submit that the scope of the present claims are clear to one having ordinary skill in the art in view of the specification and experiment examples.

Independent Claims 1, 7 and 19 recite, in part, that the claimed chewing gum includes less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect. The present claims are rejected because the Patent Office alleges that the phrase "less than the typical amount" is unclear as to what amount is necessary for use in the claimed chewing gum. In response, Applicants respectfully submit an Affidavit under 37 C.F.R. §1.132 ("*Affidavit*" attached hereto as Exhibit A), which evidences that one having ordinary skill in the art would understand the metes and bounds of Claims 1, 7 and 19.

As supported by the Affidavit, one having ordinary skill in the art one would understand that in view of the specification the phrase "less than the typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect" refers to a smaller effective amount of medicament provided in the claimed chewing gum that can achieve the same bioequivalent effect as a larger typical or standard amount of that same medicament taken orally (e.g. swallowed in a tablet or capsule). The typical or standard amounts of a medicament or active agent given in capsule or table forms are usually pre-determined standard amounts in a given industry (e.g. pharmaceutical, food) known by the skilled artisan for achieving a particular objective (e.g. alleviate a headache, increase alertness).

The specification teaches that the claimed invention is intended to apply to a wide range of drugs and agents (page 8, lines 22-33), and one of ordinary skill in the art would understand that absolute amounts of the active agents in gum can depend upon the agent given and the result to be achieved. While exemplary amounts have been provided in the specification in certain instances, for example at page 9 at lines 1-25; as indicated at page 9, lines 26-31, exact dosing regimens will depend on the agent or medicament, the person taking the medicament and the desired result.

Nevertheless, one having ordinary skill in the art would understand and be able to readily determine what these "typical amounts" of a medicament or drug given in a tablet or capsule form are. For example, for FDA approved drugs, typical or standard amounts would be the approved amounts. In fact, the typical or standard amounts are generally pre-defined and uniform in the pharmaceutical or food industry. Otherwise, how could any product be dispensed to the public at large or a physician or other healthcare provider dispense any pharmaceutical compound. The literature is replete with documentation on what is typically or commonly administered to treat a disorder. Consequently, those skilled in the art readily know or can determine what this amount is.

The amount of medicament used in the claimed gum formulation would clearly be the amount that delivers the bioequivalent of an approved dosage and will be less than the standard amount given in a capsule or tablet because of the improved absorption efficiency through the oral mucosa. Where different dosages are approved and used, various gum compositions would deliver bioequivalent amounts for the different approved dosages. For other agents, typical or standard amounts can easily be identified by one having skill by reading the ingredient listing on a package insert or by testing using various analytical techniques such as chromatography. The specific amount of an medicament agent incorporated into a gum for delivering a bioequivalent amount will be less than the pre-determined amount given in a tablet or capsule and can be ascertained by one skilled in the art using available methods.

Furthermore, Applicants respectfully submit that the numerous examples and experiments set forth in the specification demonstrate the claimed chewing gum having less than the typical amount of a medicament to achieve a bioequivalent effect of a swallowed medicament. As discovered by the Applicants, the administration of the medicament or agent

via a chewing gum through the buccal cavity can provide an increased effect than when the same medicament or agent is taken through enteral or oral administration (e.g. swallowed via capsules or tablets). For example, this is demonstrated with the caffeine study of Experiment 2 comparing the bioequivalent effect/bioavailability of caffeine in consumers' bloodstream after chewing caffeine containing gum versus swallowing caffeine pills. These examples demonstrate that less caffeine can be provided in the claimed product than that that is typically ingested, for example, through No Doze, and still achieve as good if not greater bioequivalent effect. In fact, Applicants are able to achieve a equivalent bioavailability utilizing an oral drug delivery system that approaches that of a parenteral administration.

In sum, Applicants respectfully submit that those skilled in the art would understand the metes and bounds of the claims when read in light of the specification and experimental examples. Based on at least these noted reasons, Applicants believe that Claims 1, 7 and 19 and Claims 2-6, 8-12, 19-22 and 26-29 that depend from Claims 1, 7 and 19 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully submit that the rejection of Claims 1-12, 19-22 and 26-29 under 35 U.S.C. §112, second paragraph, is improper and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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Dated: March 7, 2006